

Inert ingredient information may be entitled to confidential treatment

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: _____

Experts In-Processing Signature: _____ Date _____ Fee Paid: Yes ___

Division management contacted on issues No _____ Yes _____ Date _____

EPA Reg. Number: 82633-IN		EPA Receipt Date: 07/14/2021								
Items for Review				Yes	No	N/A*				
1	Application Form (EPA Form 8570-1) signed & complete including package type			<input checked="" type="checkbox"/>						
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			<input checked="" type="checkbox"/>						
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A) Technical, XXXXXXXXXX & impurities		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center;">yes</th> <th style="text-align: center;">no</th> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	yes	no	<input type="checkbox"/>	<input type="checkbox"/>			
yes	no									
<input type="checkbox"/>	<input type="checkbox"/>									
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			<input checked="" type="checkbox"/>						
	Certificate and data matrix consistent			<input checked="" type="checkbox"/>						
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center;">yes</th> <th style="text-align: center;">no</th> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	yes	no	<input type="checkbox"/>	<input type="checkbox"/>			
yes	no									
<input type="checkbox"/>	<input type="checkbox"/>									
	If applicable, is there a letter of Authorization for exclusive use only.									
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					<input checked="" type="checkbox"/>				
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			<input checked="" type="checkbox"/>						
5	a) Selective Method (Fee category experts use)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center;">yes</th> <th style="text-align: center;">no</th> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	yes	no	<input checked="" type="checkbox"/>	<input type="checkbox"/>			
yes	no									
<input checked="" type="checkbox"/>	<input type="checkbox"/>									
	b) Cite-All (Fee category experts use)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center;">yes</th> <th style="text-align: center;">no</th> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	yes	no	<input type="checkbox"/>	<input type="checkbox"/>			
yes	no									
<input type="checkbox"/>	<input type="checkbox"/>									
	c) Applicant owns all data (Fee category experts use)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center;">yes</th> <th style="text-align: center;">no</th> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	yes	no	<input type="checkbox"/>	<input type="checkbox"/>			
yes	no									
<input type="checkbox"/>	<input type="checkbox"/>									
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			<input checked="" type="checkbox"/>						
7	Is the data package consistent with PR Notice 86-5			<input checked="" type="checkbox"/>						
8	Notice of Filing included with <u>petitions</u>					<input checked="" type="checkbox"/>				

Inert ingredient information may be entitled to confidential treatment


9	If applicable for conventional applications, <u>reduced risk rationale</u>			
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:
Documentation: Pass
Required forms are complete

Inerts: Technical, [REDACTED] & impurities only, no inerts to review

PRN 11-3: Pass
MRID 515847

Overall Status: Pass



7/27/2021

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



United States Environmental Protection Agency

Washington D.C. 20460

July 28, 2021

Office of Chemical Safety
and Pollution Prevention

SHARDA CROP CHEM LIMITED

640

HOCKESSIN, DE 19707-0640

Report of Analysis for Compliance with PR Notice 11-3

Thank you for your submittal of 14-JUL-21. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-3. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
82633-XX	July 14, 2021	82633-XX.20210714.V1

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature

S. K. Theodorakis

Name (typed)

Agent for Sharda Cropchem Ltd.

Title

July 14, 2021

Date

(302) 510-0039/tim.t@wagnerreg.com

Phone / Email



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sharda Cropchem Ltd. , c/o Wagner Regulatory Assoc. Inc., P.O. Box 640, Hockessin, DE 19707	EPA Registration Number/File Symbol 82633-xx
Active Ingredient(s) and/or representative test compound(s) lambda-cyhalothrin (PC 128897)	Date
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food/Feed Crop and Terrestrial Nonfood Crop/Noncrop	Product Name Sharda Lambda-Cyhalothrin Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
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SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>S. K. Theodorakis</i>	Date July 14, 2021	Typed or Printed Name and Title S. K. Theodorakis, Authorized Agent
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: July 14, 2021	EPA Reg. No./ File Symbol: 82633-XX	Page 1 of 5
Applicant's/Registrant's Name and Address: Sharda Cropchem Ltd. c/o Wagner Regulatory Associates Inc. P.O. Box 640, 7217 Lancaster Pike, Suite A Hockessin, DE 19707	Product: Sharda Lambda-Cyhalothrin Technical	
Ingredient: Lambda-cyhalothrin (PC 128897)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC					
830.1550, 830.1600	Product identity, composition/Description of materials Used to Produce the Product	51584701	Sharda Cropchem Ltd.	OWN	
830.1620	Description of Production Process	51584701	Sharda Cropchem Ltd.	OWN	
830.1670	Discussion of Formation of Impurities	51584701	Sharda Cropchem Ltd.	OWN	
830.1700	Preliminary Analysis	51584702	Sharda Cropchem Ltd.	OWN	
830.1750	Certification of Limits	51584701	Sharda Cropchem Ltd.	OWN	
830.1800	Enforcement Analytical Method	51584702	Sharda Cropchem Ltd.	OWN	
830.6302	Color	51584703	Sharda Cropchem Ltd.	OWN	
830.6303	Physical State	51584703	Sharda Cropchem Ltd.	OWN	
830.6304	Odor	51584703	Sharda Cropchem Ltd.	OWN	
830.6313	Stability to Normal & Elevated Temperatures	51584714	Sharda Cropchem Ltd.	Waiver	
830.6314	Oxidation/Reduction	51584704	Sharda Cropchem Ltd.	OWN	
830.6315	Flammability	51584705	Sharda Cropchem Ltd.	OWN	
830.6316	Explosability	51584705	Sharda Cropchem Ltd.	OWN	
830.6317	Storage Stability	51584707	Sharda Cropchem Ltd.	OWN	
830.6319	Miscibility	51584714	Sharda Cropchem Ltd.	Waiver	
830.6320	Corrosion Characteristics	51587407	Sharda Cropchem Ltd.	OWN	
830.6321	Dielectric Voltage Breakdown	51584714	Sharda Cropchem Ltd.	Waiver	
830.7000	pH	51584708	Sharda Cropchem Ltd.	OWN	
830.7050	UV/Visible Absorption	51584709	Sharda Cropchem Ltd.	OWN	
830.7100	Viscosity	51584714	Sharda Cropchem Ltd.	Waiver	
830.7200, 830.7220	Melting Point/Boiling Point	51584710	Sharda Cropchem Ltd.	OWN	
830.7300	Relative Density	51584711	Sharda Cropchem Ltd.	OWN	
830.7370	Dissociation Constant	51584712	Sharda Cropchem Ltd.	OWN	
830.7520	Particle Size Distribution	51584714	Sharda Cropchem Ltd.	Waiver	
830.7550	Octanol Water Partition Coefficient	51584714	Sharda Cropchem Ltd.	PL	

Signature 	Name and Title S. K. Theodorakis, Agent for Sharda Cropchem Ltd.	Date July 14, 2021
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Applicant's/Registrant's Name and Address: Sharda Cropchem Ltd. c/o Wagner Regulatory Associates Inc. P.O. Box 640, 7217 Lancaster Pike, Suite A Hockessin, DE 19707	Product: Sharda Lambda-Cyhalothrin Technical	
Ingredient: Lambda-cyhalothrin (PC 128897)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
830.7840, 830.7860	Solubility	51584713, 51584714	Sharda Cropchem Ltd.	OWN, PL		
830.7950	Vapor Pressure	51584714	Sharda Cropchem Ltd.	PL		
870.1100	Acute Oral Toxicity	Cite All	Refer below	PAY		
870.1200	Acute Dermal Toxicity					
870.1300	Acute Inhalation Toxicity					
870.2400	Primary Eye Irritation					
870.2500	Primary Dermal Irritation					
870.2600	Dermal Sensitization					
Generic Data	Generic Data					BONIDE PRODUCTS, LLC (4)
				SYNGENTA CROP PROTECTION, LLC (100) & (10182)	PAY	
				NUFARM AMERICAS, INC. (228)	PAY	
				THE SCOTTS COMPANY (239)	PAY	
			BAYER CROPSCIENCE LP (264)	PAY		
			FMC CORPORATION (279)	PAY		
			MACDERMID AGRICULTURAL SOLUTIONS, INC. (4000)	PAY		
			BASF CORPORATION (499)	PAY		
			INTERVET INC D/B/A MERCK ANIMAL HEALTH (773)	PAY		
			MCLAUGHLIN GORMLEY KING COMPANY (1021)	PAY		
			PACIFIC CHEMICAL DIV PACE NATIONAL CORP (4389)	PAY		
			S.C. JOHNSON & SON, INC. (4822)	PAY		
			HELENA AGRI-ENTERPRISES, LLC (5905)	PAY		

Signature 	Name and Title S. K. Theodorakis, Agent for Sharda Cropchem Ltd.	Date July 14, 2021
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Ingredient: Lambda-cyhalothrin (PC 128897)		

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			LONZA, LLC (6836)	PAY	
			J.R. SIMPLOT COMPANY (8917)	PAY	
			CHEMSICO A DIVISION OF UNITED INDUSTRIES CORP. (9688)	PAY	
			ADAMA MAKHTESHIM LTD. MAKHTESHIM-AGAN OF NORTH AMERICA (11678)	PAY	
			DREXEL CHEMICAL COMPANY (19713)	PAY	
			NUFARM LIMITED NUFARM AMERICAS, INC. (35935)	PAY	
			ALBAUGH, LLC (42750)	PAY	
			CONTROL SOLUTIONS, INC. (53883)	PAY	
			VALENT U.S.A. LLC (59639)	PAY	
			SIPCAM AGRO USA, INC. (60063)	PAY	
			CORTEVA AGRISCIENCE LLC (62719)	PAY	
			MANAGEMENT CONTRACT SERVICES, INC. (63823)	PAY	
			JESMOND HOLDING AG (64321)	PAY	
			PYRETHROID WORKING GROUP (64977)	PAY	
			MAKHTESHIM AGAN OF NORTH AMERICA, INC. (66222)	PAY	
			SPRAY DRIFT TASK FORCE (66607)	PAY	
			CERTIS USA, LLC (70051)	PAY	
			UPL NA, INC. (70506)	PAY	
			ISK BIOSCIENCES CORP. (71512)	PAY	
			LG CHEM, LTD. (71532)	PAY	

Signature 	Name and Title S. K. Theodorakis, Agent for Sharda Cropchem Ltd.	Date July 14, 2021
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Ingredient: Lambda-cyhalothrin (PC 128897)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE, LLC (71754)	PAY	
			AGRICULTURAL REENTRY TASK FORCE (71755)	PAY	
			NON-DIETARY EXPOSURE TASK FORCE (NDEF) (73223)	PAY	
			FIFRA ENDANGERED SPECIES TASK FORCE, LLC (77389)	PAY	
			HELM AGRO US, INC. (74530)	PAY	
			RESIDENTIAL EXPOSURE JOINT VENTURE (REJV) (74888)	PAY	
			AGRICULTURAL HANDLER EXPOSURE TASK FORCE (75234)	PAY	
			WINFIELD SOLUTIONS, LLC (83222)	PAY	
			GAT MICROENCAPSULATION GMBH (84575)	PAY	
			GENERIC ENDANGERED SPECIES TASK FORCE (84653)	PAY	
			ARCANA, LLC (84930)	PAY	
			KAIZEN TECHNOLOGIES, LLC (86363)	PAY	
			TF HOLDINGS I, LLC (86461)	PAY	
			ARGITE, LLC (87373)	PAY	
			AGROMARKETING CO, INC. (87845)	PAY	
			SMARTVET USA, INC. (88050)	PAY	
			LIBERTY CROP PROTECTION, LLC (89168)	PAY	

Signature 	Name and Title S. K. Theodorakis, Agent for Sharda Cropchem Ltd.	Date July 14, 2021
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WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: July 14, 2021	EPA Reg. No./ File Symbol: 82633-XX	Page 5 of 5
Applicant's/Registrant's Name and Address: Sharda Cropchem Ltd. c/o Wagner Regulatory Associates Inc. P.O. Box 640, 7217 Lancaster Pike, Suite A Hockessin, DE 19707	Product: Sharda Lambda-Cyhalothrin Technical	
Ingredient: Lambda-cyhalothrin (PC 128897)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			CENTRAL GARDEN & PET COMPANY (89459)	PAY	
			COUNCIL FOR THE ADVANCEMENT OF PYRETHROID HUMAN RISK (89813)	PAY	
			EXTREMIS, LLC (91127)	PAY	

Signature



S. K. Theodorakis

Name and Title

S. K. Theodorakis, Agent for Sharda Cropchem Ltd.

Date

July 14, 2021

 <div style="display: inline-block; text-align: center;"> United States Environmental Protection Agency Washington, DC 20460 </div>		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 82633-XX		2. EPA Product Manager Jacquelyn Herrick	
4. Company/Product (Name) Sharda Cropchem Ltd. / Sharda Lambda-Cyhalothrin Technical		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include Zip Code) Sharda Cropchem Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640, 7217 Lancaster Pike Suite A Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No.: 74530-23 Product Name: Lambda-Cyhalothrin TC	
Section - II			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Notification - Explain below. <input checked="" type="checkbox"/> Other - Explain below.			
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) PRIA R333 – New Technical Grade Active Ingredient			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Package wgt container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) HDPE lined drums
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Mini-bulk, Bulk	
		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name S. K. Theodorakis		Title Agent for Sharda Cropchem Ltd.	Telephone No. (Include Area Code) (302) 510-0039 (tim.t@wagnerreg.com)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent for Sharda Cropchem Ltd.	
4. Typed Name S. K. Theodorakis		5. Date July 14, 2021	

Submitted Electronically via CDX

May 23, 2020

Document Processing Desk
Attn: Jacquelyn Herrick, PM 3
Registration Division
U.S. Environmental Protection Agency
Office of Pesticide Programs (7505P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501



**Subject: Sharda Lambda-Cyhalothrin Technical
EPA File Symbol 82633-IN (Decision – 577182)
Revised Basic Formulation CSF**

Dear Ms. Herrick,

Wagner Regulatory Associates, Inc., as agent for Sharda Cropchem Ltd., Company (EPA Co. 82633), is submitting a revised Basic Formulation CSF for the above referenced pending new manufacturing use product application. The revisions were to make corrections per email communication from CITAB reviewer Dehui Duan on May 23, 2022. The following documents were submitted electronically via the EPA CDX PSP portal:

- Letter from Sharda Cropchem Ltd. appointing Wagner Regulatory Associates, Inc. as its agent
- Proposed Basic Formulation CSF – with corrections

If you have any additional questions concerning this application, please contact me at tim.t@wagnerreg.com or call 302-635-7289.

Respectfully submitted,



S. K. Theodorakis
Agent for Sharda CropChem Ltd.

Enclosures

DATA TRANSMITTAL DOCUMENT**1. Name and Address of Submitter****Sharda Cropchem Ltd**

c/o Wagner Regulatory Associates

P.O. Box 640, 7217 Lancaster Pike, Suite A

Hockessin, DE 19707

EPA Company No. 85678

2. Regulatory Action In Support Of Which This Package Is Submitted

Application for Registration

Sharda Lambda-Cyhalothrin Technical

3. Transmittal Date

July 14, 2021

4. List of Submitted Studies

MRID

51584701	Lambda-Cyhalothrin Technical Product Identity and Composition, Description of Materials, Manufacturing Process, Discussion of Formation and Toxicity of Impurities and Certified Limits; OCSPP 830.1550, 830.1600, 830.1620, 830.1670, 830.1750; 100 pages
51584702	Five Batch Analysis of Lambda-Cyhalothrin Technical; Study No. G17324; OCSPP 830.1700; 830.1800; 363 pages
51584703	Determination of Appearance (Color, Odor and Physical State) of Lambda-Cyhalothrin Technical; Study No. G17730; OCSPP 830.6302, 830.6303, 830.6304; 27 pages.
51584704	Oxidation/Reduction: Chemical Incompatibility of Lambda-Cyhalothrin Technical; Study No. G17731; OCSPP 830.6314; 26 pages
51584705	Determination of Flammability of Lambda-Cyhalothrin Technical; Study No. G17732; OCSPP 830.6315; 24 pages
51584706	Determination of Explosive Properties of Lambda-Cyhalothrin Technical; Study No. G17747; OCSPP 830.6316; 34 pages
51584707	Accelerated Storage Stability Test By Heating At Elevated Temperatures and Packing Stability of Lambda-Cyhalothrin Technical; Study No. G17733; OCSPP 830.6317, 830.6320; 86 pages
51584708	Determination of pH of 1% (w/v) Aqueous Suspension/Solution of Lambda-Cyhalothrin Technical; Study No. G17735; OCSPP 830.6700; 28 pages
51584709	UV-Absorption Spectra of Lambda-Technical; Study No. G17748; OCSPP 830.7050; 38 pages
51584710	Determination of Melting Point of Lambda-Cyhalothrin Technical; Study No. G17737; OCSPP 830.7200; 28 pages
51584711	Determination of Density, Relative Density and Specific Gravity of Lambda-Cyhalothrin Technical; Study No. G17740; OCSPP 830.7300; 31 pages
51584712	Determination of Dissociation Constant(s) of Lambda-Cyhalothrin Technical; Study No. G17739; OCSPP 830.7370; 37 pages
51584713	Determination of Solubility of Lambda-Cyhalothrin Technical in Organic Solvents; Study No. G17743; OCSPP 830.7840; 30 pages
51584714	Sharda Lambda-Cyhalothrin Technical Product Chemistry – Group B: Request for Waiver and Citation of Data for Certain Physical / Chemical Properties Data; OCSPP 830.6313; 830.6319; 830.6321; 830.7100; 830.7520; 830.7550; 830.7840; 830.7950; 5 pages

Company Name:	Sharda Cropchem Ltd.		

Company Official: S. K. Theodorakis_____
Authorized Agent_____
Signature**Company Contact:** S. K. Theodorakis_____
Authorized Agent

(302) 510-0039 / tim.t@wagnerreg.com

Phone / Email

Submitted Electronically via CDX

July 14, 2021

Document Processing Desk (REGFEE)
Attn: Jacquelyn Herrick, PM 3
Registration Division
U.S. Environmental Protection Agency
Office of Pesticide Programs (7505P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501



Subject: Sharda Cropchem Ltd. (Company No. 82633)
Application to Register a Technical Grade Active Ingredient
PRIA Category R333
Primary Brand Name: Sharda Lambda-Cyhalothrin Technical

Dear Ms. Herrick,

Wagner Regulatory Associates, Inc., as agent for Sharda Cropchem Ltd., Company (EPA Co. 82633), is requesting registration of the above reference product containing the currently registered active ingredient lambda-cyhalothrin (PC code 128897). In support of this request, the following documents and studies are being submitted electronically via the EPA CDX PSP portal:

- Letter from Sharda Cropchem Ltd. appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Registration (8570-1)
- Confidential Statement of Formula (8570-4)
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35) - Internal and Public versions
- Data Transmittal Document
- Data Reports as Outlined in the Transmittal Document
- Draft Label
- Certification with Respect to Label Integrity
- Receipt Confirming Payment of PRIA fee for category R333 - \$20,830 (credit for fee paid previously for withdrawn application - payment ID 26QU2DGP).

Please do not hesitate to contact me by email at tim.t@wagnerreg.com or by phone at 302-510-0039 if you have any questions or require additional information concerning this new product registration application.

Respectfully submitted,



S. K. Theodorakis
Agent for Sharda CropChem Ltd.

Enclosures

From: notification@pay.gov
To: [Tim Theodorakis](#)
Subject: Pay.gov Payment Confirmation: PRIA Service Fees
Date: Friday, January 8, 2021 11:28:17 AM



An official email of the United States government

Pay.gov logo



Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 26QU2DGP
Agency Tracking ID: 76065901516
Transaction Type: Sale
Transaction Date: 01/08/2021 11:28:10 AM EST
Account Holder Name: Wagner Regulatory Associates
Transaction Amount: \$20,830.00
Card Type: AmericanExpress
Card Number: *****2008

Registration Number:
Company Name: Sharda Cropchem Ltd.
Company Number: 82633
Action Code: R333

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



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Sharda Cropchem Limited

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Regd. Office : Prime Business Park, Dashrathlal Joshi Road, Vile Parle (W),
Mumbai - 400056, India.
www.shardacropchem.com



ISO 9001: 2015 Reg. No: 702949
CIN: L51909MH2004PLC145007



December 9, 2020

To: Whom it May Concern

Re: Sharda Cropchem Ltd. - EPA Co. No. 82633 - Letter of Authorization

This letter serves as notification that Sharda Cropchem Ltd., has appointed Wagner Regulatory Associates, Inc. (WRA, Inc.) to serve as the Agent on our company's behalf regarding State and/or Federal regulatory matters as determined by Sharda Cropchem Ltd. The following employees of Wagner Regulatory Associates, Inc. are authorized to act on our behalf:

James Wagner
Email: james@wagnerreg.com
Phone: 302-635-7290

S. K. Theodorakis
Email: tim.t@wagnerreg.com
Phone: 302-510-0039

Carrie Nolan
Email: carrie@wagnerreg.com
Phone: 302-635-7632

Katie Woodall
Email: ktwoodall@wagnerreg.com
Phone: 302-753-5305

Keeva Shultz
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Phone: 302-635-7281

Rachel Hardie
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Catherine Parmeter
Email: catherine@wagnerreg.com
Phone: 410-920-8756

Annette Marine
Email: annette.marine@wagnerreg.com
Phone: 302-635-7283

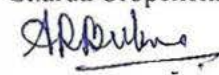
Correspondence can be addressed to any of the above employees at:

Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707-0640

Thank you for your time and assistance. Please feel free to contact Wagner Regulatory Associates, Inc. should you have any questions.

Respectfully submitted,

Sharda Cropchem Ltd


Ashish Bubna
(Director)



cc: WRA, Inc.